

Patent Claims

DRAFTING
VERSION

1. Method for the differential-diagnostic early detection and detection, for the assessment of the severity, and for the assessment of the success of a therapeutic treatment of sepsis and severe infections, in particular sepsis-like systemic infections, characterized in that the content of at least one peptide prohormone other than procalcitonin and/or of a partial peptide derived therefrom, which is not the mature hormone obtainable from said peptide prohormone, is determined in a sample of a biological fluid of a patient, and the presence of a sepsis or sepsis-like systemic infection, its severity and/or the success of a therapeutic treatment are determined from the detected presence and/or amount of the determined peptide prohormone.
2. Method according to Claim 1, characterized in that the peptide prohormone is selected from the group consisting of pro-gastric-releasing peptide (proGRP), pro-endothelin-1 (pro-END), pro-brain-natriuretic peptide (pro-BNP), pro-atrial-natriuretic peptide (pro-ANP or pro-ANF), pro-leptin, pro-neuropeptide-Y, pro-somatostatin, pro-neuropeptide-YY or pro-adrenomedullin (pro-ADM).
3. Method according to either of Claims 1 and 2, characterized in that by the determination a partial peptide is detected which differs from the known complete peptide prohormone by the lack of a dipeptide at the amino terminus thereof, as it can be cleaved off by dipeptidyl-aminopeptidase IV (DP IV or DAP IV or CD26) from the end of a peptide.
4. Method according to Claim 3, characterized in that

the dipeptide is an Xaa-Pro dipeptide, Xaa representing the amino-terminal amino acid of the complete prohormone peptide.

5. Method according to any of Claims 1 to 4,
characterized in that said determination of said
peptide prohormone is carried out as an immunoassay
or precipitation assay, and a diagnosis of the
presence of sepsis or severe sepsis-like infections
is made if the concentration of the peptide
prohormone determined is significantly higher than
the values for the same prohormone observed in
healthy normal persons.

10

15. 6. Method for the differential-diagnostic early
detection, for the detection, and for the assessment
of the severity and for the assessment of the
success of a therapeutic treatment of a sepsis and
sepsis-like systemic infections, characterized in
that the content of dipeptidyl-peptidase IV (DP IV;
dipeptidyl-aminopeptidase IV; DAP IV or CD26) is
determined in a serum or plasma sample of a patient
and the presence of a sepsis or sepsis-like systemic
infection is diagnosed on the basis of a
concentration of dipeptidyl-peptidase IV which is
significantly reduced compared with healthy normal
subjects.

20

25

7. Procalcitonin 3-116 prepared by genetic engineering.

8. Method for the preparation of procalcitonin 3-116 by
genetic engineering, comprising
- inserting a cDNA sequence coding for the 114
30 amino acids of procalcitonin 3-116 into a
suitable vector,
- transforming suitable host cells with the vector
formed so that they express procalcitonin 3-116,

- working up said host cells,
- recovering a fraction containing the expressed procalcitonin 3-116, and
- obtaining from said fraction said procalcitonin 5 3-116 as a product prepared by genetic engineering in at least 90% purity by chromatographic purification.

9. Use of recombinant procalcitonin 3-116 as a calibrator in procalcitonin assays or for the preparation of therapeutics for the prevention and treatment of sepsis and sepsis-like systemic infections.

10. Method for the measurement of procalcitonin 3-116 as an indication-independent diagnostic parameter.

DO NOT DESTROY - PENDING